
Remarks

Claims 1-8, 11-18, and 32-47 are currently pending in the instant Application.

Claim 34 has been amended to address an issue with antecedent basis. Claims 1, 6-7, and 11-17 also have been amended. Support for the claim amendments is found in the claims as filed and throughout the specification, for example, in the figures and at page 10 of the Application as filed. Applicants submit that no new matter is introduced by way of the amendments submitted herein. Applicants respectfully request entry of the amendments.

I. Interview Summary

Applicants acknowledge with appreciation the Examiner's helpful interview on November 19, 2003. In the interview Applicants' representative and the Examiner discussed the claim amendments submitted in the After Final response to office action filed October 1, 2003. In addition, Applicants' representative and the Examiner discussed additional support in the specification for the proposed amendments. Applicants submit that in light of the clarifications made during the interview and in light of comments and amendments submitted herein, the claims are now in form for allowance.

II. Double Patenting Rejection

In the Office Action, claims 1-8, 11-18, and 32-47 were rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 and 27-30 of U.S. Patent 6,327,410 ("410 Patent") and over claims 22-38 and 57-58 of U.S. Patent 6,023,540 ("540 Patent").

While Applicants disagree that the currently pending claims are obvious over those of the '410 and '540 Patents, in order to expedite allowance of the application, Applicants will consider a terminal disclaimer if necessary and appropriate when there is an indication of otherwise allowable subject matter.

III. § 112, ¶ 1 Rejections

Claims 32-47 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. More specifically, it is stated in the Office Action that the claimed relationship of the second optical signature with the first chemical functionality is not described. Applicants respectfully traverse.

Claim 32 is directed to beads of separate subpopulations carrying a first chemical functionality capable of changing a first optical signature, wherein the beads “further comprise a second optical signature which is encoded with a description of said first chemical functionality carried by said subpopulation.”

Claim 40 is directed to a chemical analysis method comprising, in part, beads of first and second subpopulations comprising “a chemical functionality capable of changing a first optical signature”, and “a second optical signature which is encoded with a description of said chemical functionality”.

To satisfy the written description requirement, the disclosure must “convey with reasonable clarity to those skilled in the art that . . . [the inventor] was in possession of the invention.” Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323 (Fed. Cir. 2000).

Here, Applicants submit that the subject matter of independent claims 32 and 40 is described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed inventions. Support for the second optical signature and its relationship to the first chemical functionality is provided at page 10 of the Application as filed. As disclosed in the Application at lines 3-7, “[t]he chemical functionality is designed so that in the presence of the analyte(s) to which it is targeted, an optical signature of the microsphere, possibly including region surrounding it, is changed.” As further disclosed at lines 18-20, the microsphere “has an optical signature that is encoded with a description of the chemical functionality.” Thus, the specification discloses a first chemical functionality capable of changing a first optical signature, wherein the beads further comprise a second optical signature which is encoded with a description of said first chemical functionality.

In addition, Applicants note that the subject matter of the claim need not be described literally or “in haec verba” in order for the specification to satisfy the written description requirement. *In re Lukach*, 442 F.2d 967, 969, 169 USPQ 795 (CCPA 1971). It is sufficient that the specification “convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that the Applicants have invented the specific subject matter later claimed.” *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 97 (CCPA 1976), *appeal after remand*, 646 F.2d 527, 209 USPQ 554 (CCPA 1981).

To this end Applicants respectfully direct the Examiner to the specification where several examples of a subpopulation of microspheres carrying chemical functionality which changes a first optical signature of the beads in the presence of targeted analytes, the microspheres in each subpopulation having a second optical signature which is encoded with a description of the chemical functionality carried by that subpopulation. For example, Applicants note that such first and second optical signatures are exemplified at p. 6, lines 10-14 and lines 30-32. Here the sensors are described as having a population of beads “which changes an optical signature of the beads in a presence of targeted analytes.” In addition, the second optical signature is exemplified in the description of beads that are “encoded using dyes that are preferably entrapped within the beads, the chemical functionality being added on surfaces”. Applicants submit that without limiting the scope of the claims, such disclosure exemplifies a subpopulation of microspheres carrying chemical functionality which changes a first optical signature of the beads in the presence of targeted analytes, beads in each subpopulation having a second optical signature which is encoded with a description of the chemical functionality carried by that subpopulation, as claimed.

In addition, other examples in the specification include figure 1 and descriptions of figure 1. As above, Applicants note that p. 10, lines 1-3 describe that the microsphere is given a chemical functionality. In addition, at p. 10, lines 18-22 are an example of one embodiment of a second encoding optical signature. In this embodiment “[t]he inventive microsphere has an optical signature that is encoded with a description of the chemical functionality.” In one embodiment, the “reporter dyes **14** are added to the microsphere **10**”.

In addition, figure 2 and its description outline an example wherein the encoding dye system and chemical functionality (with which the target analyte associates) can be attached in two distinct steps. Alternatively, “[t]he microspheres may be purchased with the desired chemical functionalities already present” and “a dye solution added to it in step **52** to encode optical signatures of the microspheres with information concerning the intended surface chemical functionalities.” Both examples demonstrated that the beads can have two components; one that is a chemical functionality that charges an optical signature in the presence of a targeted analyte and the other a second optical signature that is encoded with a description of the chemical functionality.

Also, Applicants respectfully submit that the specification is replete with examples of dyes, for example, that can be used as encoding optical signatures (see p. 12, line 4 to p. 13, line 19), and examples of chemical functionalities with which a target analyte may associate (see p. 13, line 26 to p. 18, line 21) and that have an optical signature that changes in the presence of a targeted analyte.

Finally, Applicants note the examples that demonstrate the use of encoding optical signatures and chemical functionalities with which a target analyte may associate and that have an optical signature that changes in the presence of a targeted analyte.

Accordingly, Applicants submit that one of skill in the art would understand that Applicants invented the subject matter claimed. Applicants respectfully submit that the disclosure complies with the written description requirement of 35 U.S.C. § 112, first paragraph.

Because claims 33-39 depend directly or indirectly from claim 32 and incorporate all the limitations of claim 32, and because claims 41-47 depend directly or indirectly from claim 40 and incorporate all the limitations of claim 40, the above argument obviates the bases for these grounds of rejection. Thus, claims 32-39 and 40-47 comply with the written description requirement. Reconsideration and withdrawal of the rejections is respectfully requested.

IV. § 112, ¶ 2 Rejections

Claims 32-47 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. More specifically, it is stated in the Office Action that the claims are not clear as to what relationship exists between the second optical signature and the first chemical functionality. Applicants respectfully traverse.

The definiteness requirement of 35 U.S.C. § 112, second paragraph, requires that each claim particularly point out and distinctly claim the subject matter that Applicants regard as their invention. That requirement is met when the scope of the claim is understood by one of ordinary skill in the art when the claim is read in light of the specification. See S3 Inc. v. nVIDIA Corp., 259 F.3d 1364, 1367 (Fed. Cir. 2001).

Applicants submit that claims 32 and 40 particularly point out and distinctly claim subject matter which Applicants regard as the invention.

Claim 32 is directed to beads of separate subpopulations carrying a first chemical functionality capable of changing a first optical signature, wherein the beads “further comprise a second optical signature which is encoded with a description of said first chemical functionality carried by said subpopulation.”

Claim 40 is directed to a chemical analysis method comprising, in part, beads of first and second subpopulations comprising “a chemical functionality capable of changing a first optical signature”, and “a second optical signature which is encoded with a description of said chemical functionality”. Accordingly, it is clear from the plain meaning of the language recited in the claims that the relationship existing between the first and second optical signature is that the chemical functionality associated with the former is encoded by the latter. Further, the scope of the claims is understood when read in light of the specification. As discussed above, support for the second optical signature and its relationship to the first chemical functionality of claim 32 and to the chemical functionality of claim 40 is provided throughout the Application as filed.

Because claims 33-39 depend directly or indirectly from claim 32 and incorporate all the limitations of claim 32, and because claims 41-47 depend directly or indirectly from claim 40 and incorporate all the limitations of claim 40, the above argument obviates the bases for these grounds of rejection. Thus, claims 32-39 and 40-47 are not indefinite. Reconsideration and withdrawal of the rejections is respectfully requested.

V. § 102(b) Rejections

Claims 1-8, 11-18, and 32-47 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 4,822,746 to Walt (“Walt I”) or U.S. Patent 5,143,853 to Walt (“Walt II”). Applicants respectfully traverse.

A. Independent Claim 1 Is Not Anticipated by Walt I or Walt II

Claim 1 is directed to an analytic chemistry system comprising a population of beads including separate subpopulations. Each subpopulation carries chemical functionality which changes a first optical signature of the beads in the presence of targeted analytes, beads in each subpopulation having a second optical signature which is encoded with a description of the chemical functionality carried by that subpopulation.

It is well settled that an anticipatory prior art reference must teach “*all of the elements and limitations* contained in the claims.” ATD Corp. v. Lydall, Inc., 159 F.3d 534, 545 (Fed.

Cir. 1998). Here, however, it is respectfully submitted that the Office has not established that Walt I and Walt II teach all of the elements of claim 1.

In particular, the Office Action points to the Walt references as describing analytical chemistry systems comprising a population of beads encoded with fluorescent dyes. However, the mere description of beads with multiple dyes on them does not describe the claimed analytic chemistry system comprising, among other things, separate subpopulations of beads each having a first optical signature and a second optical signature which is encoded with a description of the chemical functionality carried by that subpopulation, because the cited passages of Walt I and II do not describe the dyes as containing encoding information regarding the identity of a particular chemical functionality.

Claim 1, therefore, stands in condition for allowance. Reconsideration and withdrawal of the § 102(b) rejection is respectfully requested.

B. Independent Claim 11 Is Not Anticipated by Walt I or Walt II

Independent claim 11 is directed to a chemical analysis method. The method comprises, in part, preparing separate subpopulations of beads, each subpopulation carrying chemical functionalities that change first optical signatures of the beads in the presence of targeted analytes. The method further comprises, in part, encoding second optical signature of the beads in each subpopulation with a description of the chemical functionalities carried by that subpopulation. The method further comprises, in part, decoding said second optical signature of the beads to identify the chemical functionalities.

In contrast, as discussed above, Walt I and Walt II disclose methods and apparatuses for the detection of an analyte of interest in a fluid sample. Here, however, it is respectfully submitted that the Office has not established that Walt I or II teach all of the elements of claim 11. In particular, as explained above, the mere description in the Walt references of beads with multiple dyes on them does not describe the claimed chemical analysis method comprising, among other things, preparing separate subpopulations of beads and encoding optical signature of the beads in each subpopulation with a description of the chemical functionalities carried by that subpopulation, because the cited passages of Walt I and II do not describe the dyes as containing any encoding information regarding the identity of a particular chemical functionality.

Claim 11, therefore, stands in condition for allowance. Reconsideration and withdrawal of the § 102(b) rejection is respectfully requested.

C. Independent Claim 32 Is Not Anticipated by Walt I or Walt II

Independent claim 32 is directed to an analytic chemistry system comprising a population of beads including separate subpopulations. The beads of each subpopulation carry a first chemical functionality capable of changing a first optical signature of the bead in the presence of a target analyte. Further, the beads of each subpopulation comprise a second optical signature which is encoded with a description of said first chemical functionality carried by said subpopulation.

Walt I and II have been discussed above. Here, however, it is respectfully submitted that the Office has not established that Walt I or II teach all of the elements of claim 32. In particular, as explained above, the mere description in the Walt references of beads with multiple dyes on them does not describe the claimed analytic chemistry system comprising, among other things, a population of beads including separate subpopulations and beads of each subpopulation comprising a second optical signature which is encoded with a description of said first chemical functionality carried by said subpopulation, because the cited passages of Walt I and II do not describe the dyes as containing any encoding information regarding the identity of a particular chemical functionality.

Claim 32, therefore, stands in condition for allowance. Reconsideration and withdrawal of the § 102(b) rejection is respectfully requested.

D. Independent Claim 40 Is Not Anticipated by Walt I or Walt II

Independent claim 40 is directed to a chemical analysis method. The method comprises, in part, a population of beads comprising a first and second subpopulation, the beads of each subpopulation comprising a chemical functionality capable of changing a first optical signature of the bead in the presence of a target analyte. The method further comprises, in part, a second optical signature which is encoded with a description of said chemical functionality carried by the bead of the subpopulation. In addition, the method comprises, in part, decoding said second optical signature of said beads to identify the first chemical functionality.

Walt I and II are discussed above. However, it is respectfully submitted that the Office has not established that Walt I or II teach all of the elements of claim 40. In particular, as

explained above, the mere description in the Walt references of beads with multiple dyes on them does not describe the claimed chemical analysis method comprising, among other things, a population of beads comprising a first and second subpopulation and a second optical signature which is encoded with a description of said chemical functionality carried by the bead of the subpopulation, because the cited passages of Walt I and II do not describe the dyes as containing any encoding information regarding the identity of a particular chemical functionality.

Claim 40, therefore, stands in condition for allowance. Reconsideration and withdrawal of the § 102(b) rejection is respectfully requested.

E. Claims Depending from Claims 1, 11, 32, and 40 Are Patentable

Because the remaining claims depend directly or indirectly from claims 1, 11, 32, or 40 and incorporate all the limitations of those claims, the above argument obviates the basis for this ground of rejection. Thus, the remaining claims are not anticipated by Walt I or Walt II. Reconsideration and withdrawal of the rejection is respectfully requested.

VI. § 102(e) Rejection

Claims 1-8, 11-18, and 32-47 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 5,814,524 to Walt et al. ("Walt III"). It is respectfully submitted that claims 1-8, 11-18, and 32-47 are not anticipated by Walt III.

A. Independent Claim 1 Is Not Anticipated by Walt III

As discussed above, claim 1 is directed to an analytic chemistry system comprising a population of beads including separate subpopulations. Each subpopulation carries chemical functionality which changes a first optical signature of the beads in the presence of targeted analytes, beads in each subpopulation having a second optical signature which is encoded with a description of the chemical functionality carried by that subpopulation.

It is well settled that an anticipatory prior art reference must teach "*all of the elements and limitations* contained in the claims." ATD Corp. v. Lydall, Inc., 159 F.3d 534, 545 (Fed. Cir. 1998). The passages of Walt II cited by the Examiner disclose an optical sensor apparatus for far-field viewing and imaging as well as for the optical detection and analytical measurement of at least one species of analyte in a remotely-positioned fluid sample. However, here there is no teaching or suggestion that each subpopulation carries a chemical functionality which changes

a first optical signature of the beads and that the beads in each subpopulation have a second optical signature which is encoded with a description of the chemical functionality.

That is, Walt III elegantly describes a sensor apparatus for detection of an analyte in a remotely-positioned fluid sample. However, the Office Action fails to establish that Walt III discloses separate subpopulations wherein the beads in each subpopulation have a second optical signature which is encoded with a description of the chemical functionality carried by that subpopulation. Instead, Walt III discloses the use of a plurality of dye reagents on a substrate surface that generate multiple signals indicative of the *presence of an analyte*. Applicants submit that this is distinct from a second optical signature encoded with a *description of the chemical functionality*, as claimed. Walt III, therefore, does not disclose the invention of claim 1.

Claim 1, therefore, stands in condition for allowance. Reconsideration and withdrawal of the § 102(e) rejection is respectfully requested.

B. Independent Claim 11 Is Not Anticipated by Walt III

As described above, claim 11 is directed to a chemical analysis method. The method comprises, in part, preparing separate subpopulations of beads, each subpopulation carrying chemical functionalities that change first optical signatures of the beads in the presence of targeted analytes. The method further comprises, in part, encoding second optical signature of the beads in each subpopulation with a description of the chemical functionalities carried by that subpopulation. The method further comprises, in part, decoding said second optical signature of the beads to identify the chemical functionalities.

Walt III is described above. However, here there is no teaching or suggesting of encoding second optical signature of the beads in each subpopulation with a description of the chemical functionalities carried by that subpopulation. That is, Walt III discloses the use of a plurality of dye reagents on a substrate surface that generate multiple signals indicative of the *presence of an analyte*. Applicants submit that this is distinct from a second optical signature of the beads in each subpopulation encoded with a *description of the chemical functionalities carried by that subpopulation*, as claimed. Walt III, therefore, does not disclose the invention of claim 11.

Claim 11, therefore, stands in condition for allowance. Reconsideration and withdrawal of the § 102(e) rejection is respectfully requested.

C. Independent Claim 32 Is Not Anticipated by Walt III

As discussed above, independent claim 32 is directed to an analytic chemistry system comprising a population of beads including separate subpopulations. The beads of each subpopulation carry a first chemical functionality capable of changing a first optical signature of the bead in the presence of a target analyte. Further, the beads of each subpopulation comprise a second optical signature which is encoded with a description of said first chemical functionality carried by said subpopulation.

Walt III is discussed above. However, here there is no teaching or suggesting beads of each subpopulation comprising a second optical signature which is encoded with a description of said first chemical functionality carried by said subpopulation. That is, Walt III discloses the use of a plurality of dye reagents on a substrate surface that generate multiple signals indicative of the *presence of an analyte*. Applicants submit that this is distinct from a second optical signature encoded with a *description of a first chemical functionality*, as claimed. Walt III, therefore, does not disclose the invention of claim 32.

Claim 32, therefore, stands in condition for allowance. Reconsideration and withdrawal of the § 102(e) rejection is respectfully requested.

D. Independent Claim 40 Is Not Anticipated by Walt III

As discussed above, independent claim 40 is directed to a chemical analysis method. The method comprises, in part, a population of beads comprising a first and second subpopulation, the beads of each subpopulation comprising a chemical functionality capable of changing a first optical signature of the bead in the presence of a target analyte. The method further comprises, in part, a second optical signature which is encoded with a description of said chemical functionality carried by the bead of the subpopulation. In addition, the method comprises, in part, decoding said second optical signature of said beads to identify the first chemical functionality.

Walt III is discussed previously. However, here there is no teaching or suggesting of a second optical signature which is encoded with a description of said chemical functionality carried by the bead of the subpopulation. That is, Walt III discloses the use of a plurality of dye reagents on a substrate surface that generate multiple signals indicative of the *presence of an analyte*. Applicants submit that this is distinct from a second optical signature encoded with a

description of the chemical functionality carried by the bead of the subpopulation, as claimed.

Walt III, therefore, does not disclose the invention of claim 40.

Claim 40, therefore, stands in condition for allowance. Reconsideration and withdrawal of the § 102(e) rejection is respectfully requested.

E. Claims Depending from Claims 1, 11, 32, and 40 Are Patentable

Because the remaining claims depend directly or indirectly from claims 1, 11, 32, or 40 and incorporate all the limitations of those claims, the above argument obviates the basis for this ground of rejection. Thus, the remaining claims are not anticipated by Walt III. Reconsideration and withdrawal of the rejection is respectfully requested.

Conclusion

Applicants respectfully submit that claims 1-8, 11-18, and 32-47 are in condition for allowance. Reconsideration and a Notice of Allowance for all pending claims is respectfully requested. Please direct any calls in connection with this application to the undersigned attorney at 415-544-7085.

Respectfully submitted,

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